IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: WAVE 3 CASES LISTED IN EXHIBIT A TO DEFENDANTS' MOTION	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

DEFENDANTS' MOTION TO EXCLUDE PEGGY PENCE, PH.D.

Defendants Ethicon, Inc.; Ethicon, LLC; and Johnson & Johnson (collectively, "Ethicon"), pursuant to Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharms.*, Inc., 509 U.S. 579, 589 (1993), move to exclude the testimony of Peggy Pence, Ph.D., in the entirety.   In support of this motion, Ethicon states:

1.   Dr. Pence is not qualified to opine about the adequacy of the device IFUs, and her methodology is unreliable.

2.   Dr. Pence is not qualified to opine that Ethicon did not meet the post-market vigilance standard of care for TVT, TVT-O, and Prolift; her methodology is unreliable; and her opinion is irrelevant.

3.   Dr. Pence is not qualified to offer opinions about the adequacy of the TVT, TVT-O or PROSIMA testing. In addition, Dr. Weber offers a number of unreliable and irrelevant opinions throughout her expert report.

4.   Dr. Pence's opinion that the TVT-O and PROSIMA labeling did not support adequate informed consent of patients is irrelevant and inadmissible.

5.   Dr. Pence's opinion that Ethicon obtained clearance to market PROSIMA based

on false or misleading statements to the FDA is speculative, irrelevant, and inadmissible.

6.   Dr. Pence's opinion that Ethicon did not act in the interest of patient safety in removing PROSIMA from the market is unreliable and irrelevant and should be excluded.

7.   Dr. Pence's opinion that Prolift was misbranded or adulterated because it was marketed without clearance is improper and irrelevant and should be excluded.

8.   Dr. Pence's opinion that Ethicon reported false and misleading information to the FDA with respect to Prolift is improper, preempted, and should be excluded.

9.   Dr. Pence should not be permitted to offer opinions about products for which she did not provide an expert report.

10.   Ethicon incorporates by reference its Memorandum in Support of its Motion to Exclude Peggy Pence, Ph.D., and the following exhibits:

Exhibit	Description
A	List of Applicable Cases
B	Dr. Pence's Prolift Report, July 17, 2014
C	Dr. Pence's TVT-O Report, July 17, 2014
D	Dr. Pence's TVT Report, Oct. 14, 2013
E	Dr. Pence's PROSIMA Report, Feb. 1, 2016
F	Dr. Pence's Supplemental TVT and TVT-O Report, Mar. 2, 2016
G	Dr. Pence's Supplemental Prolift and PROSIMA Report, Mar. 3, 2016
H	Transcript of Dr. Pence's Mar. 24, 2016 Deposition
I	*Label and Instructions for Use for Medical Devices*, Global Harmonization Task Force, Sept. 16, 2011
J	*Device Labeling Guidance #G91-1 (Blue Book Memo)*, FDA Office of Device Evaluation, Mar. 8, 1991

K   Transcript of Dr. Pence's Mar. 3, 2016 Deposition

L   Plaintiffs' Designation and Disclosure of Expert Witnesses

WHEREFORE, FOR THESE REASONS and as more fully set forth in Ethicon's supporting memorandum of law, Ethicon respectfully requests that this Court enter an order granting Ethicon's Motion to Exclude Peggy Pence, Ph.D.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this day, I electronically filed this document with the

clerk of the court using the CM/ECF system, which will send notification of this filing to

CM/ECF participants registered to receive service in this MDL.

/s/   *Christy D. Jones*
Christy D. Jones